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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,947	01/04/2001	Bruce A. Lee	14907003310	4527

20350 7590 12/16/2002

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/16/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/754,947

Applicant(s)

LEE ET AL

Examiner

Padmavathi v Baskar

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-- Th MAILING DATE of this communication app ars on the cover sh et with th corr spond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-16,19-23,25-29,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) 31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-16,19-23 and 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,3,5-16,19-23,25-29,31 and 32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

LYNETTE R. F. SMITH *lrf*
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 12.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Response to the amendment

1. The amendment filed on 9/16/02 is entered. Claims 2, 4, 17, 18, 24 and 30 have been canceled. Claims 1, 5-7, 10, 11, 13, 19, 20, 22, 25 and 27 have been amended. Claims 1, 3, 5-16, 19-23, 25-29 and 31-32 are pending in the application. Claims 31-32 are withdrawn from consideration as a non-elected invention, said election being made in Paper # 8.
2. The examiner acknowledges the various amendments to the specification in response to the Office action mailed on 4/9/02.

Rejections withdrawn

3. In view of amendment to the claims 5 and 6, the rejection under 35 U.S.C. 112, second paragraph is withdrawn
 4. In view of amendment to the claim 1 and cancellation of claim 2, the rejection of claim 1 as being anticipated by Graham et al 1984 (Eur.J.Clin. Microbiol, 3:210-212) is withdrawn as Graham et al 1984 does not disclose a method specifically detecting a strain of bacillus surface array protein using specific first and second antibodies that binds to the surface protein.
 5. In view of amendment to the claims 1, 5-7, 10, 11, 13, 19 and 20 and cancellation of claims 2, 4, 17, 18, the rejection of claims 1, 3, 5-16, 19-21 under 35 U.S.C. 102(b) as being anticipated by Yu H 1998, Journal of Immunological Methods, Vol. 218, 1-8 is withdrawn as Yu H 1998 does not disclose a method specifically detecting a strain of bacillus surface array protein using specific first and second antibodies that binds to the surface protein.
 6. In view of amendment to the claims 1, 5-7, 10, 11, 13, 19 and 20 and cancellation of claims 2, 4, 17, 18, the rejection of claims 1-21 under 35 U.S.C. 103(a) as being unpatentable Phillips et al FEMS Microbiology Immunology 1988, 47: 169-178 in view Toumelin et al 1995 Journal of Bacteriology 1995, 177: 614-620 is withdrawn as the prior art does not teach a
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method specifically detecting a strain of bacillus surface array protein using specific first and second antibodies that binds to the surface protein.

Rejections maintained

7. The rejection of claims 1, 5, 7, 8, 10, 11, 13-16, 19 –21 under 35 U.S.C. 102(b) as being anticipated by Ligler et al 1996, U.S. Patent 5,496,700 is maintained as set forth in the previous Office action.

Claims are drawn to a method of detecting the presence or absence of *B. anthracis* in a test sample using first and second antibodies.

Ligler et al disclose a method of detecting the presence or absence of *B. anthracis* in a test sample using a first antibody, monoclonal antibodies FDF –IB9 (example 2) that binds to *B. anthracis* and detection agent comprising detectable label (see abstract and claims). Monoclonal antibodies FDF –IB9, specific for *B. anthracis* were immobilized on a solid support, fibers (see example 2) as a capture reagent.

Nile red and *B. anthracis* in the presence of mouse immunoglobulins was used as a secondary detectable label antibody that binds to a different epitope on the anthracis (see example 7). Clinical samples suspected to have *B. anthracis* were used in this assay (see example 7). This method detects 3 cells /ul (see abstract and figures 1 and 7) and appear to be sensitive. Thus, the prior art anticipated the claimed invention. In the absence of evidence to the contrary the disclosed prior art antibodies bind to surface array protein. Characteristics such as amino acid sequence SEQ.ID.NO: 1 would be inherent in the preparations of Ligler since the samples contain encapsulated spores, which comprise surface array proteins (examples 2 and 7). Applicant's use of the open-ended term "having" in the claims fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. See *In re Horvitz*, 168 F.2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and *Ex parte Davis et al.*, 80 U.S.P.Q. 448 (PTO d. App. 1948).

This rejection is maintained for essentially the same reasons as the rejection of claims under this statutory provision, as set forth above in the last Office action. Applicants' arguments filed on 9/11/02 have been fully considered but they are not deemed to be persuasive.

Applicant asserts that the prior art of record do not teach or disclose using an antibody specific for SEQ.ID.NO: 1 and brings Examiner's attention to column 8, lines 61-64 of Ligler et al. The examiner has carefully looked the recited column and disagrees with the applicant for the following reasons.

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(1). The mouse monoclonal antibody, FDF –1B9 is specific for capsular material of B.anthraxis **vegetative cells** which includes the surface array protein (sap) in the S.layer of the vegetative cells and therefore, the monoclonal antibodies inherently bind to SEQ.ID.NO: 1

(2) Vegetative cells do not contain the spores and therefore the monoclonal first antibody which is specific binds to surface array protein present on the bacteria since the monoclonal antibodies (first antibody) specifically binds to surface array protein and mouse immunoglobulins in the presence of Nile red as a secondary detectable antibody that binds to a different epitope on the anthracis (see example 1 in column 8). Taken together, the prior art reads on the claimed invention. Therefore, this rejection is maintained.

8. The rejection of claims 1, 3, 5-16, 19-23, 25-29 under 35 U.S.C. 103(a) as being unpatentable over Ligler et al 1996, U.S.Patent 5,496,700 as discussed above and in view of Litman et al 1983, U.S.Patent 4,391,904 is maintained.

The Prior art as discussed above does not teach that the reagents antibodies and detection reagent are put together in the form of a kit. Litman et al teach a kit for use in immunoassays comprising antibodies and detection reagents for detection of varieties of microorganisms including B.anthraxis (abstract, claims and column 30, line29). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to keep all the ingredients disclosed by the prior art (Ligler et al) in the form of a compact kit since kits are easy to transport and convenient to work with and does not require trained technicians to perform the test on site. An artisan of ordinary skill would have been motivated in applying the art disclosed by Ligler et al to keep the reagents together in the form of a kit because kits would help in diagnosing anthracis conveniently and do not require trained technical support since it comes with instructions to use. Although Litman et al did not teach that the samples are collected by cyclonic device, it is well known to a person of ordinary skill in the art of immunology that the air samples would be collected by the disclosed device. Kits were well known in the market for testing or diagnosing varieties of diseases and come with the instructions. Therefore, the claimed invention is prima facie obvious in view of Ligler et al and Litman et al absent any convincing evidence to the contrary.

This rejection is maintained for essentially the same reasons as the rejection of claims under this statutory provision, as set forth above in the last Office action. Applicants' arguments filed on 9/11/02 have been fully considered but they are not deemed to be persuasive.

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Applicant asserts that Ligler does not teach or suggest using antibody specific for SEQ.ID.NO: 1 to detect B.anthraxis and brings Examiner's attention to column 8, lines 61-64 of Liger et al. Further, the applicant states that addition of Litman et al do not teach or describe antibodies specific for SEQ.ID.NO: 1 and detection reagents. The examiner disagrees with the applicant because Liger et al teach mouse monoclonal antibody, FDF -1B9, specific for capsular material of B.anthraxis vegetative cells used as first antibody that binds to surface array protein (sap) in the S.layer of the vegetative cells and mouse immunoglobulins in the presence of Nile red as a secondary detectable antibody that binds to a different epitope on the anthracis. Therefore, addition of Litman et al reference is not a primary reference and it is used as a secondary reference to support the kit since Ligler et al taught first, second and other detectable labels. Therefore, the examiner has established a prima facie obvious rejection using the cited prior art of record. Therefore, this rejection is maintained.

New Rejections based on amendment

Claim Rejections - 35 USC 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 1, 3, 5-16, 19-23, 25-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete.

Applicant claims a method for detecting the presence of Bacillus anthracis surface array protein using specific first antibody and second antibody. It is not clear how this method detects or

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measures the presence of surface array protein without using a labeled first or second antibody.

As written, the claim does not detect the presence of surface protein.

Similarly, claim 22 is rejected as being vague. It is not clear how to detect specifically a strain of Bacillus in a test sample using a kit that contains the first antibody and second antibody that can specifically bind to surface array protein.

Claims 1 and 22 are vague and unclear in the recitation of " surface array protein (SEQ.ID.NO: 1)". It is also not clear whether " (SEQ.ID.NO: 1)".) is intended to be a limitation of the claim. Applicant is advised to remove the parenthesis.

Applicant states in the amendment filed on 9/11/02 Paper # 11 that the amended claim is clear in reciting, "detecting whether the surface array protein is bound to the antibody with a second antibody that binds to the surface array protein." The examiner disagrees with the applicant because in order to measure the complex formed between the test sample and first antibody and there after second antibody, either the first or second antibody or the test sample should be labeled either with an enzyme, dye or radioactive substance in order to detect whether the surface array protein is bound to the antibody or not.

Claim Rejections - 35 USC 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. ~~Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Mesnage et al 1997~~

Molecular Microbiology 23 (6), 1147-1155.

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Mesnage et al 1997 disclose a method of detecting a strain of B. anthracis in a test sample by contacting the supernatant containing surface array protein (SAP) with polyclonal rabbit anti-sap antibodies (first antibody) and detecting the surface array protein present in the sample using gold anti rabbit antibodies as secondary antibodies that bind to the first antibody as a complex (see figure 5 and page 1154, left column, second paragraph and third paragraph) by an immunoblot and by electron microscopy. The prior art also discloses a method of detecting the presence of anthracis containing SAP proteins in the supernatants of cell cultures by contacting the sample with rabbit anti-sap antibodies and secondary anti rabbit antibody (see page 1154, protein analysis). Thus, the prior art anticipated the claimed invention. In the absence of evidence to the contrary the disclosed prior art reads on the claimed invention since the SAP proteins in the supernatant of cultures bind to the specific anti-SAP antibodies. Characteristics such as amino acid sequence SEQ.ID.NO: 1 would be inherent in the preparations of culture supernatant since the samples contain surface array proteins (examples 2 and 7). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Status of Claims

13. No claims are allowed.

Conclusion

14. This application contains claims 31-32 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

11/21/02
